HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region M33600

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 00-NWJ-14

December 23, 1999

Mr. David M. Miller
President
Miller's Homecare Services
18 Utter Avenue
Hawthorne, NJ 07506

Dear Mr. Miller:

During an inspection of your oxygen repacking facility located at 18 Utter Avenue Hawthorne, New Jersey, on November 22 and 24, 1999, an Investigator from the Food and Drug Administration (FDA) documented deviations from the current Good Manufacturing Practice Regulations (cGMPs) for the prescription drug product Oxygen, USP. Regulations governing your operations are found in Title 21 of the Code of Federal Regulations, Parts 210 and 211 (21 CFR Parts 210 and 211). Deviations from these regulations were noted on the Form FDA 483, List of Inspectional Observations, issued to you at the close of the inspection.

The inspection revealed that your oxygen repacking operations are considered to be adulterated within the meaning of Section 501 (a)(2)(b) of the Federal Food, Drug and Cosmetic Act (the Act), in that the methods used in, or the facility and/or control used for, transfilling of gas and liquid oxygen, are not in conformance with cGMPs as follows:

1. Failure to assure that the Oxygen Compressed, USP, that you manufacture meets the standards of identity and strength for Oxygen, USP, because you do not assay the finished product "D" and "E" size high-pressure cylinders of Oxygen Compressed, USP, for identity and strength.

2. Failure to properly calibrate equipment. For example:

   a. The Servomex Oxygen Analyzer, used for the assay of Oxygen, USP, is not properly calibrated, in that your firm did not utilize certified oxygen to set the instrument's span and certified Nitrogen required to calibrate "zero" on the meter.

b. Failure to provide documentation that the Servomex 570A Oxygen Analyzer is calibrated prior to use.
c. Failure to perform and document that weekly checks of the Servomex 570A Oxygen Analyzer's filter element for dirt and moisture contamination are being conducted.
d. Failure to obtain on-site a current manual for the Servomex 570A, which contains the current calibration procedure.

3. Failure to perform the appropriate prefill operations on each high-pressure cylinder, prior to filling. For example:

   a. The vacuum gauge used in the evacuation of the cylinders is broken. We observed that the vacuum gauge on the filling manifold was resting at "-5" inches of Mercury.
   b. The vacuum pump used in the evacuation of the cylinders is not calibrated.

4. Failure to assign a new and unique finished product lot number for each manifold filling sequence of Oxygen Compressed, USP (each sequence is for up to five cylinders). We observed one lot number being assigned to an entire day's production. For example, on 11/01/99, one lot number was assigned to [redacted] filled cylinders and on 11/05/99, one lot number was assigned to [redacted] filled cylinders.

5. Lack of an established quality assurance procedure outlining the designated individuals responsible for approving or rejecting components, for labeling and releasing finished products, and the reviewing and approving established procedures, as they relate to your medical oxygen transfilling operations.

6. Failure to establish a training program for employees responsible for the transfilling of liquid and gas oxygen.

7. Failure to assure that the high-pressure cylinders of Oxygen Compressed, USP, that your firm manufactures are properly filled to contain the declared volume (liters) and will not exceed the Safe Service Pressure at 70°F. For example:

   a. Failure to calibrate the two manifold gauges.
   b. Failure to utilize a cylinder thermometer to determine cylinder filling temperature
   c. Failure to fill the cylinders according to a pressure / temperature chart.

8. Failure to adequately complete production records, "OXYGEN TRANSFILL LOG," in that the records lack the checks for:

   a. Cylinder Color;
   b. Appropriate labeling;
   c. Filling temperature and pressure;
   d. Pre-fill valve inspection; and
   e. Signature and date of review and approval by a second qualified individual.

9. Failure to maintain the Oxygen Concentrators that your firm distributes according to the manufacturer's recommended maintenance requirements. These maintenance requirements must be performed to assure adequate Oxygen purity and the proper functioning of the unit.

Additionally, the high-pressure cylinders observed at your firm are considered misbranded in that the labels used to identify these units lacked the official name of the product (Oxygen Compressed, USP); the required prescription drug caution statement; and the name and address of the firm that currently fills the cylinders. We observed that the cylinders in current use at your firm contain the names of firms that previously filled the cylinders.

The above items are not intended to be an all-inclusive list of violations. It is your responsibility to ensure adherence with each requirement of the cGMPs as it applies to your operations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. You should notify this office in writing within 15 working days of receipt of this letter regarding the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Jill A. Mielziner, Acting Compliance Officer, at the address and telephone number above.

Sincerely yours,

Douglas I. Ellsworth
District Director